CLAIMS

We claim:

1. A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is covered with a coating for release of at least one biologically active material, wherein said coating comprises an undercoat having an outer surface and comprising a polymeric material incorporating an amount of biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat which covers less than the entire outer surface of the undercoat, said topcoat comprising a polymeric material substantially free of pores and porosigens.

2. The device of claim 1 wherein the topcoat covers less than the entire undercoat while the device is implanted.

3. The device of claim 1 wherein the topcoat covers less than the entire undercoat before the device is implanted.

4. The device of claim 1 wherein the topcoat covers less than the entire undercoat before the device is implanted and while the device is implanted.

5. The device of claim 1 wherein the polymeric material of the undercoat is a hydrophobic elastomeric material and wherein the polymeric material of the topcoat is a biostable, biocompatible material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material.

6. The device of claim 1 wherein the topcoat reduces a burst release of the biologically active material as compared to a coated device without the topcoat.

7. The device of claim 1 wherein the biologically active material is heparin.

8. The device of claim 1 wherein the polymeric material of the topcoat is selected from the group consisting of fluorosilicone, polyethylene glycol (PEG), polysaccharides, phospholipids and combinations thereof.

9. The device of claim 8 wherein the polymeric material is fluorosilicone.

10. The device of claim 8 wherein the polymeric material is polyethylene glycol (PEG).

11. The device of claim 1 wherein the topcoat covers from about 5% to 95% of the surface of the undercoat.

12. The device of claim 11 wherein the topcoat covers from about 20% to 85% of the surface of the undercoat.

13. The device of claim 1 wherein the topcoat has an average thickness of about 1 to 7 microns.

14. The device of claim 13 wherein the topcoat has an average thickness of about 1 to 5 microns.

15. The device of claim 1 wherein the topcoat has an average thickness of about the average particle size of the biologically active material.

16. The device of claim 1 wherein the device is an expandable stent.

17. The device of claim 1 wherein the polymeric materials of the topcoat and the bottom coat are water permeable.

18. A stent for implantation in a vascular lumen comprising a tubular body having open ends and a sidewall and a coating on at least a part of a surface of said sidewall, said coating further comprising an undercoat having an outer surface and comprising a polymeric material incorporating an amount of a biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat comprising a polymeric material selected from the group consisting of fluorosilicone and polyethylene glycol (PEG), wherein said topcoat covers less than the entire outer surface of the undercoat and wherein said topcoat is substantially free of pores and porosigens.

19. The stent of claim 18 wherein the topcoat covers less than the entire undercoat while the device is implanted.

20. The stent of claim 18 wherein the topcoat covers less than the entire undercoat before the device is implanted.

21. The stent of claim 18 wherein the topcoat covers less than the entire undercoat before the device is implanted and while the device is implanted.

22. The stent of claim 18 wherein the polymeric material of the undercoat is a hydrophobic elastomeric material and wherein the polymeric material of the topcoat is a biostable, biocompatible material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material.

23. The stent of claim 18 wherein the topcoat reduces a burst release of the biologically active material as compared to a coated stent without the topcoat.

24. The stent of claim 18 wherein the stent is self-expandable and the sidewall comprises at least one opening

therein and wherein the coating conforms to said sidewall in a manner that preserves said opening.

25. The stent of claim 18 wherein the biologically active material is heparin.

26. The stent of claim 18 wherein the topcoat covers from about 20% to 85% of the surface of the undercoat.

27. The stent of claim 18 wherein the topcoat has an average thickness of about 1 to 5 microns.

28. The stent of claim 18 wherein the topcoat has an average thickness of about the average particle size of the biologically active material.

29. A method of coating an implantable stent prosthesis having at least a portion which is implantable into the body of a patient, wherein at least a part of the stent portion is covered with a coating for release of at least one biologically active material; the method comprising:

(a) applying an undercoat comprising a polymeric material and the biologically active material to the stent portion; and

(b) applying a topcoat over the surface of the undercoat, said topcoat comprising a polymeric material, substantially free of pores and pore-forming materials.

30. The method of claim 29 wherein the polymeric material of the undercoat is a hydrophobic elastomeric material and wherein the polymeric material of the undercoat is a biostable, biocompatible material which provides long term non-thrombogenicity to the stent portion during and after release of the biologically active material.

31. The method of claim 29 wherein the polymeric material of the topcoat is selected from the group consisting

of fluorosilicone, polyethylene glycol (PEG), polysaccharides, phospholipids and combinations thereof.

32. The method of claim 29 wherein the topcoat covers from about 5% to 95% of the surface of the undercoat.

33. The method of claim 32 wherein the topcoat covers from about 20% to 85% of the surface of the undercoat.

34. The method of claim 29 wherein the topcoat has an average thickness of about the average particle size of the biologically active material.

35. The method of claim 29 wherein the topcoat has an average thickness of about 1 to 7 microns.

36. The method of claim 35 wherein the topcoat has an average thickness of about 1 to 5 microns.

37. The method of claim 29 wherein the polymeric material of the topcoat is a polymer which is incompatible with the polymeric material of the undercoat such that a topcoat covering less than the entire surface of the undercoat is formed.

38. The method of claim 29 which further comprises applying a poor solvent to the topcoat to shrink the polymeric material to form a topcoat which covers less than the entire surface of the undercoat.

39. The method of claim 29 wherein the Young's modulus of the polymeric material of the undercoat and the Young's modulus of the polymeric material of the topcoat are different.

40. The method of claim 39 wherein the Young's modulus of the polymeric material of the topcoat is greater than the Young's modulus of the polymeric material of the undercoat.

41. A method of using an implantable stent prosthesis comprising:

(a) providing an implantable stent prosthesis having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is covered with a coating for release of at least one biologically active material, wherein said coating comprises an undercoat having an outer surface and comprising a polymeric material incorporating an amount of biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat which covers less than the entire outer surface of the undercoat said topcoat comprising a polymeric material substantially free of pores and porosigens;

(b) implanting the device into the body of a patient; and

(c) allowing the biologically active material to be released such that the topcoat limits the burst release of the biologically active material.

42. The method of claim 41 wherein the topcoat remains on the undercoat after release of the biologically active material.

43. The method of claim 41 wherein the topcoat covers less than the entire undercoat while the device is implanted.

44. The method of claim 41 wherein the topcoat covers less than the entire undercoat before the device is implanted.

45. The method of claim 41 wherein the topcoat covers less than the entire undercoat before the device is implanted and while the device is implanted.

46. The method of claim 41 wherein the polymeric material of the undercoat is a hydrophobic elastomeric material and wherein the polymeric material of the topcoat is a biostable, biocompatible material which provides long term non-thrombogenicity to the stent portion during and after release of the biologically active material.

47. The method of claim 41 wherein the polymeric material of the topcoat is selected from the group consisting of fluorosilicone, polyethylene glycol (PEG), polysaccharides, phospholipids and combinations thereof.

48. The method of claim 41 wherein the topcoat covers from about 5% to 95% of the surface of the undercoat.

49. The method of claim 41 wherein the topcoat has an average thickness of about the average particle size of the biologically active material.

50. The method of claim 41 wherein the topcoat has an average thickness of about 1 to 7 microns.